K080690

APR 25 2008

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Address:	1800 Triplett Blvd. Akron, Ohio 44306
Telephone Number:	330-475-8600
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	03 March 2008

B. Device Information

Trade Name:	Manta Ray™ Anterior Cervical Plate (ACP) System
Common Name:	Anterior Spinal Fixation System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR **888.3060**)
Device Classification:	**Class II** (per 21 CFR **888.3060**) *Panel:* **Orthopedic**, *Product Code:* **KWQ,** *Panel Code:* **87**
Material Composition:	Implant grade Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136
Device Description:	The Manta Ray™ ACP System is an anterior cervical plate fixation system. The system consists of a number of plates and screws. The plates feature a normal lordotic curvature as well as a transverse plane curvature for anatomic fit and are available in a variety of lengths for one to four level configurations. Screws are available in fixed and variable angle styles to create rigid or semi-rigid constructs as well as multiple lengths to fit individual patient pathologies. All implants are machined from implant grade titanium alloy, Ti-6Al-4V (ELI) per ASTM F-136.
Intended Use:	The Manta Ray™ ACP System is an anterior cervical plate that is intended for temporary stabilization of the cervical spine from C2-C7 due to the following indications: Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), Spondylolisthesis, Trauma (i.e. fracture/dislocation), Tumor, Spinal stenosis, Deformity (i.e. scoliosis, kyphosis and/or lordosis), Pseudoarthrosis, Failed previous fusion
Performance Data:	Static and fatigue testing was performed to characterize the stiffness, strength and fatigue life of Manta Ray™ ACP System
Predicate Device:	X-Spine Systems - Spider Cervical Plating System (K052292 - October 21, 2005) Theken Surgical, LLC - Tether™ ACFS (K010466 - May 16, 2001)

C. Substantial Equivalence

Theken Spine, LLC believes that the Manta Ray™ ACP System is substantially equivalent to other legally marketed predicate devices. Establishment of equivalence is based on the same indications and contraindications for use as well as similarities in design concept, the use of established known materials, feature comparisons, mechanical testing and engineering analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

Theken Spine
% Mr. Dale Davison
Vice President of Engineering
1800 Triplett Blvd
Akron, OH 44306

Re: K080690
Trade/Device Name: Manta Ray™ Anterior Cervical Plate (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 3, 2008
Received: March 11, 2007

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K080690**

Device Name: Manta Ray ACP System

Indications For Use:

The Manta Ray™ ACP System is an anterior cervical plate that is intended for temporary stabilization of the cervical spine from C2-C7 due to the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture/dislocation)
- Tumor
- Spinal stenosis
- Deformity (i.e. scoliosis, kyphosis and/or lordosis)
- Pseudoarthrosis
- Failed previous fusion

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080690